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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,561	10/22/2001	Yoshio Jo	763-29	3304

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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07/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/069,561	Applicant(s) JO ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,36-55,57-60 and 62-74 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34,36-55,57-60 and 62-74 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

Following the reversal of the examiner at the Board of Patent Appeals and Interferences, prosecution has been re-opened in this case. Claims 34, 36-55, 57-60, and 62-74 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 34, 36-40, 42-55, 57-60, and 62-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* (European Patent Application No. EP 0 956 869 A2) in view of Jo *et al.* (Japanese Patent Application No. JP 2000-256958).

The Soe *et al.* reference discloses a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8% (See Sections 0016 to 0017). The sealant preferably further comprises enzymes such as thrombin, and proteins, which include fibrinogen and coagulation factor XIII. All components of the tissue sealant are biodegradable (See Sections 0015 and 0029). A method of preparing the tissue sealant is disclosed (See Section 0039).

The Soe *et al.* reference does not disclose a process for the etherification of low-substituted cellulose fibers, nor does it teach a tissue sealant in the form of a fiber or fabric.

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The Jo *et al.* reference teaches a soluble cellulose fiber having a hemostatic action. Natural or regenerated cellulose fibers are treated with a sodium hydroxide solution and subsequently reacted with a monochloroacetic acid solution to produce cellulose with a degree of etherification ranging from 0.5% to 1.0% (See provided English-language abstract).

It would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the references of the prior art into the object of the rejected claims. The Soe *et al.* patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe *et al.* patent. The Jo *et al.* patent discloses such methods of production. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA 1960), the idea of combining them flows logically from their having been individually taught in the prior art." In this case, both the Soe *et al.* and Jo *et al.* references deal with wound-treating compositions that comprise carboxymethyl cellulose with a low degree of etherification. With the combined disclosure of the prior art, it becomes obvious to one of ordinary skill in the art that carboxymethyl cellulose, as a vehicle for substances such as thrombin, fibrinogen, and Factor XIII, can take various forms, whether it is the sealant of Soe *et al.* or the fiber of Jo *et al.* Furthermore, it is the position of the examiner that as the

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collective disclosure of the prior art has made obvious the instantly claimed invention, claimed features, such as fibrinomer absorptivity, maximum platelet agglutination rate, agglutination percentage, adhered cell count, and mean hemostasis time, would be present as well. As a composition cannot be separated from its properties, so it is that the prior art, having disclosed the same composition with the same components would also possess the same characteristics as claimed by the appellant, even if the prior art is silent with respect those characteristics. Thus, the instantly claimed invention is *prima facie* obvious.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soe *et al.* (European Patent Application No. EP 0 956 869 A2) in view of Jo *et al.* (Japanese Patent Application No. JP 2000-256958) and Edwardson *et al.* (U.S. Patent No. 5,962,026)

The Soe *et al.* reference discloses a tissue sealant that comprises carboxymethyl cellulose, with a degree of etherification of preferably 0.5% to 1.5% and most preferably 0.6% to 0.8% (See Sections 0016 to 0017). The sealant preferably further comprises enzymes such as thrombin, and proteins, which include fibrinogen and coagulation factor XIII. All components of the tissue sealant are biodegradable (See Sections 0015 and 0029). A method of preparing the tissue sealant is disclosed (See Section 0039).

The Soe *et al.* reference does not disclose a process for the etherification of low-substituted cellulose fibers, nor does it teach a tissue sealant in the form of a fiber or fabric, nor does it teach that proteins, nor does it teach the chemical bonding of proteins to cellulosic fibers through treatment with carbodiimide.

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The Jo *et al.* reference teaches a soluble cellulose fiber having a hemostatic action. Natural or regenerated cellulose fibers are treated with a sodium hydroxide solution and subsequently reacted with a monochloroacetic acid solution to produce cellulose with a degree of etherification ranging from 0.5% to 1.0% (See provided English-language abstract).

The Edwardson *et al.* patent teaches a fibrin composition useful as a surgical sealant to provide hemostasis (See Abstract). The patent discloses that a thrombin-like enzyme may be immobilized on a support through various activation chemistries, including carbodiimide groups. Suitable supports for immobilization include cellulose and cellulose derivatives (See Column 8, Line 63 to Column 9, Line 35).

It would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the references of the prior art into the object of the rejected claims. The Soe *et al.* patent states that the use of low-substituted carboxymethylcellulose is preferred for the disclosed invention. Therefore, one of ordinary skill in the art would seek to find methods of producing low-substituted cellulose ether in order to carry out the best mode of the invention described in the Soe *et al.* patent. The Jo *et al.* patent discloses such methods of production. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA 1960), the idea of combining them flows logically from their having been individually taught in the prior art." In this case, both the Soe *et al.* and Jo *et al.* references deal with wound-treating

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compositions that comprise carboxymethyl cellulose with a low degree of etherification.

With the combined disclosure of the prior art, it becomes obvious to one of ordinary skill in the art that carboxymethyl cellulose, as a vehicle for substances such as thrombin, fibrinogen, and Factor XIII, can take various forms, whether it is the sealant of Soe *et al.* or the fiber of Jo *et al.*

Edwardson *et al.* provides a motivation, to combine with the other prior art references, disclosing that immobilization of a thrombin-like enzyme can prevent contamination of the composition (See Edwardson *et al.*, Column 8, Lines 57-62). Therefore, one of ordinary skill in the art would seek to bond proteins to a substrate such as the cellulose fibers and sealants of the prior art in order to produce an improved product that is less susceptible to contamination. Further treatment of the material with carbodiimide according to Edwardson *et al.* may be carried out for these reasons. As all three prior art references teach the use of hemostatic compositions having a cellulose support, they are analogous and one of ordinary skill in the art would therefore have a reasonable expectation of success in combining the references.

Furthermore, it is the position of the examiner that as the collective disclosure of the prior art has made obvious the instantly claimed invention, claimed features, such as fibrinomer absorptivity, maximum platelet agglutination rate, agglutination percentage, adhered cell count, and mean hemostasis time, would be present as well. As a composition cannot be separated from its properties, so it is that the prior art, having disclosed the same composition with the same components would also possess the same characteristics as claimed by the appellant, even if the prior art is silent with respect those characteristics. Thus, the instantly claimed invention is *prima facie* obvious.

Remarks

In accordance to the issues raised by the Board in the reversal of the examiner in this case, the reference cited by the Board on Page 7 of the decision was deemed to be applicable prior art and therefore, a new prior art rejection has been set forth by the examiner. It is important to note that this reference, the Jo *et al.* reference, is an intervening reference, published between the filing of the PCT application from which this case derives and the Japanese patent application to which that PCT application claims priority. Therefore, the examiner strongly urges the applicants to perfect their claim for foreign priority and submit a certified translation of their foreign priority application to this Office as this will be the best way to overcome the new prior art rejections set forth in this Office Action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

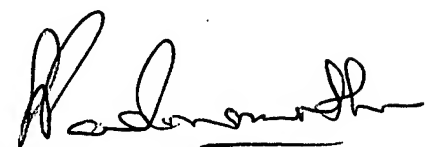
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